K011496

AUG 1 0 2001

RICHARD WOLF
Medical Instruments Corporation

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: May 14, 2001
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Cysto-Urethroscopes "E-Line", existing of: Sheaths, Obturators, Inserts, Attachments, and Forceps	Model number: 8650.xxx,8652.xxx, 8660.xxx.....see section 4: 'submitted devices'
Common name: Cysto-Urethroscopes and accessories	**Classification Name:** Cysto-Urethroscopes and accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-amend.	1 Cysto-Urethroscopes	1 Richard Wolf
2 K980302	2 Resectoscopes, Instruments and Accessories E-Line	2 Richard Wolf

1.0 Description

The Cysto-Urethroscopes "E-Line" submission consists of Sheaths, Obturators, Inserts, Adapters and Optical Forceps.

2.0 Intended Use

The Cysto-Urethroscopes "E-Line" and Accessories are used to visualize and manipulate bladder, urethra and ureter via natural passages.

The **sheath** is used to house the endoscope, inserts, and attachments. The sheath provides irrigation, water supply and drainage.

The **obturator/viewing obturator** serves to insert the sheaths atraumatically. If a viewing obturator is used, the insertion can be observed.

The **Inserts** are used to guide and angle flexible auxiliary instruments.

The **attachments** (adapters) serve to connect endoscope and sheath.

The **forceps/optical forceps and scissors** are used for endoscopically controlled grasping, manipulating, cutting, dissecting and removal of tissue, bladder stones and foreign bodies via natural and surgically created passages.
Optical forceps with unipolar HF connections are used for coagulation by means of high frequency currents to treat minor hemorrhages.

3.0 Technological Characteristics

The submitted Cysro-Urethroscopes " E-Line" are equivalent in function and intended use/indication to pre-amendment devices. They are optimized and improved in dimensions and material due to technical progress. They have a modern ergonomic design "E-Line" same a Resectoscope "E-Line", cleared in pre-market notification K980302.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to pre-amendment devices and to existing devices (K980302) sold by Richard Wolf.

5.0 Performance Data

The submitted devices are in conformance with the relevant provisions of the Medical Device Directive 93/42/EEC. This are pending approval by a conformity assessment procedure according to Annex II and VII.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Aug 1, 2001

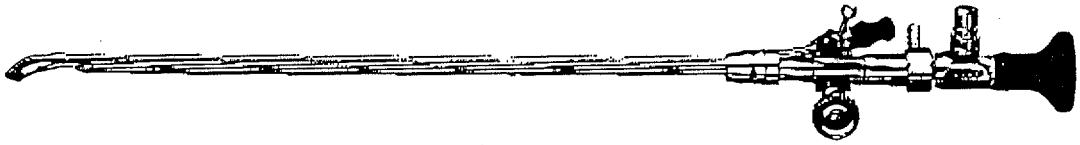
Robert L. Casarsa
Quality Assurance Manager

Retro Guiding Insert

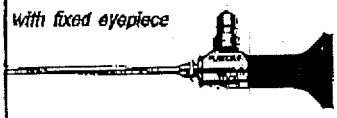
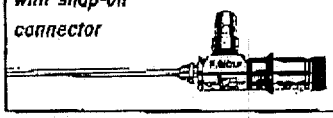
for cysto-urethroscope 8650
with telescope 4 mm, 70°, 110°

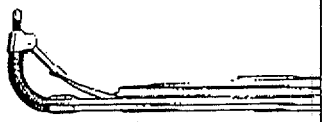
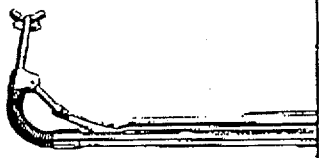
Retro-Steuerungs-Einsatz

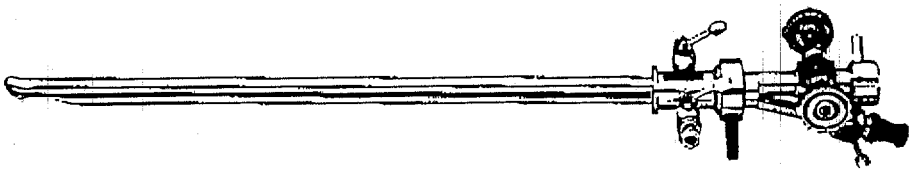
für Cysto-Urethroskop 8650
mit Optik 4 mm, 70°, 110°



AUTOCLAVE
134° C / 273° F

Optiken *Telescopes*			Standard-Version *Standard*	mit gesteigerter Bildgröße und Objektfeld *with enlarged image and objective field*	Steck-Okulartrichter *Snap-on connector*
mit festem Okular *with fixed eyepiece* 	4 mm	70°	8650.435	8650.405	
		110°		8650.409	
mit snap-on Verschluß *with snap-on connector* 	4 mm	70°		8650.407	8885.901 oder drehbar *or rotatable* 8885.902

Retro-Steuerungs-Einsatz *Retro guiding insert*		Zur Koagulation oder Probe-Exzision am Blasendach *For coagulation or biopsy of the upper bladder wall*	
	passend in Schäfte *for sheaths*	Koagulations-Knopf-Elektrode, 6 Charr. *Coagulating button electrode, 6 Fr.* 	PE-Zange, 7 Charr. *Biopsy forceps, 7 Fr.* 
8650.29	21 + 23 Charr. / *Fr.*	823.06	829.07



AUTOCLAVE
134° C / 273° F

Zur Ureter-Schienung *For ureteric stents*	Kennfarbe *Colour code*	passend in Schaft *for sheath*	Type *Type*
Schaft mit Obturator *Sheath with obturator*	schwarz / *black*	25 Charr. / *Fr*	8650.061
hierzu / *also:*			
Einsatz, einläufig, Durchlaß 15 Charr. *Insert with one instrument port, capacity 15 Fr.*			8650.27

NEW 8650.064

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K011496
Cysto-Urethroscope "E-Line" and Accessories
Dated: May 14, 2001
Received: May 15, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): K011496

Device Name: Cysto-Urethroscope 'E-Line' and Acessories

Intended Use: The Cysto-Urethroscopes 'E-Line' and Accessories are used to visualize and manipulate the bladder, urethra and ureter via natural passages.

The **sheath** is used to house the endoscope, inserts, and attachments. The sheath provides irrigation, water supply and drainage.

The **obturator/viewing obturator** serves to insert the sheaths atraumatically. If a viewing obturator is used, the insertion can be observed.

The **inserts** are used to guide and angle flexible auxiliary instruments.

The **attachments** (adapters) serve to connect endoscope and sheath.

The **forceps/optical forceps and scissors** are used for endoscopically controlled grasping, manipulating, cutting, dissecting and removal of tissue, bladder stones and foreign bodies via natural and surgically created passages.
Optical forceps with unipolar HF connections are used for coagulation by means of high frequency currents to treat minor hemorrhages.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011496

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter ____